U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

D1248 B

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Irving Wengrod, President
Geriatric Products, Inc.
72 Division Place
Brooklyn, NY 11222

March 11, 1997

Ref: 45-NYK-97

Dear Mr. Wengrod:

During an inspection of your firm on January 27 through February 6, 1997, our investigator determined that your firm manufactures various protective restraints which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

On March 4, 1996, a final rule was published in the *Federal Register* (a copy of the *Federal Register* announcement is enclosed) stating that the Food and Drug Administration is revising the classification regulations for protective restraints and wheelchair accessories intended for use as restraints, by revoking the existing exemptions for these devices from premarket notification (510(k) submission) and current good manufacturing practices (CGMP) regulations. All manufacturers and initial distributors of protective restraints and wheelchair accessories intended for use as restraints already commercially marketed on or before September 3, 1996 were required to file premarket notification submissions by September 3, 1996. All protective restraints and wheelchair accessories intended for use as restraints that are introduced or delivered for introduction into interstate commerce on or after September 3, 1996, are required to be manufactured in compliance with the CGMP regulations.

The above-referenced inspection revealed that your protective restraint devices are misbranded under Section 502(o) of the Act, in that premarket notices or other information respecting the devices were not provided to the Food and Drug Administration ("the FDA") as required by Section 510(k). Until the devices are determined by the FDA to be substantially equivalent, they are automatically classified by statute into Class III. Therefore, the devices are also adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g).

The inspection also revealed that your protective restraint devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice for Medical Devices Regulations, as specified in Title 21, *Code of Federal Regulations*, Part 820, as follows:

1. Failure to prepare and maintain device master records for your protective restraints that include, or refer to the location of, information such as device and component specifications; production process specifications; and quality assurance procedures and specifications.

2. Failure to maintain device history records for your protective restraints to demonstrate that the devices are manufactured in accordance with the device master records and which include information such as the dates of manufacture; the quantity manufactured; the quantity released for distribution; and any control number used.

3. Failure to have any written procedures for and to maintain any records of finished device inspections to assure that device specifications are met.

4. Failure to establish any written manufacturing procedures and controls to assure that the devices conform to applicable specifications.

5. Failure to establish written procedures for and to conduct planned and periodic audits of the quality assurance program to verify compliance with the quality assurance program.

6. Failure to validate significant manufacturing processes for your protective restraints to assure that these processes will consistently produce devices that meet predetermined specifications.

7. Failure to establish a complaint handling system for the review, evaluation, and filing of all complaints.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and its regulations. The specific violations noted in this letter and in the Form FDA 483 (copy enclosed) issued to and discussed with you at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering awards for contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Bruce A. Goldwitz, Compliance Officer.

Sincerely,

Diana Amador

Diana Amador
Acting District Director

Enclosures: Form FDA 483 dated February 3, 1997
Federal Register/Vol. 61, No. 43/Monday, March 4, 1996/Pages 8432-8440
Draft Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Devices

cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140/QA file
cc: HFR-NE150
cc: HFR-NE1510/Elizabeth Jacobson
cc: HFA-224
cc: HFI-35/No purging required
cc: HFC-210 (CFN 2431955)
cc: HFZ-306
cc: EF (Geriatric Products, Inc.)
cc: warning letter file
cc: chrono./circ.
cc: BAG